

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
11 March 2004 (11.03.2004)

PCT

(10) International Publication Number
WO 2004/019955 A1

(51) International Patent Classification⁷: **A61K 31/58**,
A61P 37/08, 11/00

(21) International Application Number:
PCT/EP2003/009622

(22) International Filing Date: 29 August 2003 (29.08.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
02019406.4 30 August 2002 (30.08.2002) EP

(71) Applicant (for all designated States except US): **ALTANA
PHARMA AG** [DE/DE]; Byk-Gulden-Str. 2, 78467 Kon-
stanz (DE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **MARX, Degenhard**
[DE/DE]; Obere Reute 15, 78345 Moos (DE). **MÜLLER,**
Helgert [DE/DE]; Zum Lerchental 1a, 78315 Radolfzell
(DE).

(74) Agent: **KRATZER, Bernd**; Altana Pharma AG,
Byk-Gulden-Str.2, 78467 Konstanz (DE).

(81) Designated States (*national*): AE, AL, AU, BA, BR, CA,
CN, CO, DZ, EC, GE, HR, ID, IL, IN, IS, JP, KR, LT, LV,
MA, MK, MX, NO, NZ, PH, PL, SG, TN, UA, US, VN,
YU, ZA, ZW.

(84) Designated States (*regional*): Eurasian patent (AM, AZ,
BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE,
BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU,
IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted
a patent (Rule 4.17(ii)) for the following designations AE,
AL, AU, BA, BR, CA, CN, CO, DZ, EC, GE, HR, ID, IL, IN,
IS, JP, KR, LT, LV, MA, MK, MX, NO, NZ, PH, PL, SG, TN,
UA, VN, YU, ZA, ZW, Eurasian patent (AM, AZ, BY, KG,
KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH,
CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU,
MC, NL, PT, RO, SE, SI, SK, TR)
- of inventorship (Rule 4.17(iv)) for US only

Published:

- with international search report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: THE USE OF THE COMBINATION OF CICLESONIDE AND ANTIHISTAMINES FOR THE TREATMENT OF ALLERGIC RHINITIS

(57) Abstract: The present invention relates to a combination of ciclesonide with antihistamines.

WO 2004/019955 A1

INTERNATIONAL SEARCH REPORT

International Application No.
EP 03/09622

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 18 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 09622

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0212235	A	14-02-2002	AU 7094701 A	18-02-2002
			BR 0113071 A	01-07-2003
			CA 2418908 A1	14-02-2002
			EP 1307449 A1	07-05-2003
			WO 0212235 A1	14-02-2002
			US 2002161006 A1	31-10-2002
US 2002115680	A1	22-08-2002	DE 10050994 A1	18-04-2002
			AU 1397502 A	29-04-2002
			BG 107688 A	30-09-2003
			CA 2425557 A1	11-04-2003
			EE 200300151 A	16-06-2003
			WO 0232899 A1	25-04-2002
			EP 1325001 A1	09-07-2003
			NO 20031693 A	28-05-2003
WO 0128562	A	26-04-2001	AU 7953100 A	30-04-2001
			BG 106512 A	29-12-2002
			BR 0014878 A	11-06-2002
			CA 2388322 A1	26-04-2001
			CN 1379674 T	13-11-2002
			CZ 20021238 A3	17-07-2002
			EP 1225902 A1	31-07-2002
			HU 0203339 A2	28-02-2003
			WO 0128562 A1	26-04-2001
			JP 2003512329 T	02-04-2003
			NO 20021898 A	22-04-2002
			SK 6922002 A3	10-09-2002
			TR 200200841 T2	22-07-2002
			ZA 200203077 A	17-12-2002
EP 0903151	A	24-03-1999	EP 0903151 A1	24-03-1999
			AU 9540098 A	12-04-1999
			BR 9812361 A	19-09-2000
			CA 2304162 A1	01-04-1999
			DE 19882573 T0	26-10-2000
			WO 9915203 A1	01-04-1999
			ES 2171356 A1	01-09-2002
			JP 2001517639 T	09-10-2001
			NO 20001459 A	21-03-2000
			PL 339541 A1	18-12-2000
			US 2002037297 A1	28-03-2002
			ZA 9808638 A	23-03-1999

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 009622

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K31/58 A61P37/08 A61P11/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02 12235 A (KATO TOMOKI ; PFIZER PHARMA (JP); SHISHIDO YUJI (JP); IKEDA TAKAFUM) 14 February 2002 (2002-02-14) claim 18 page 25, line 31 page 23, line 19 - line 31 ---	1, 15
X	US 2002/115680 A1 (PIEPER MICHAEL PAUL ET AL) 22 August 2002 (2002-08-22) page 12, paragraph '0174! page 12, paragraph '0177! page 13, paragraph '0179! ---	1, 15
Y	WO 01 28562 A (NISHIBE YOSHIHISA ; NAGANO ATSUSHIRO (JP); TEIJIN LTD (JP); TAKANASH) 26 April 2001 (2001-04-26) claims 1-23 ---	1-18
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

6 November 2003

Date of mailing of the international search report

20/11/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Beranová, P

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 09622

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	SCHMIDT BERNHARD M W ET AL: "The new topical steroid ciclesonide is effective in the treatment of allergic rhinitis" JOURNAL OF CLINICAL PHARMACOLOGY, vol. 39, no. 10, October 1999 (1999-10), pages 1062-1069, XP008024248 ISSN: 0091-2700 * page 1062, abstract *	1-18
Y	EP 0 903 151 A (ASTA MEDICA AG) 24 March 1999 (1999-03-24) * page 2, paragraphs '0002!', '0006!' and '0007!' *	1-18
Y	MATTILA MAURI J ET AL: "Variations among non-sedating antihistamines: Are there real differences?" EUROPEAN JOURNAL OF CLINICAL PHARMACOLOGY, vol. 55, no. 2, April 1999 (1999-04), pages 85-93, XP002260456 ISSN: 0031-6970 page 90, left-hand column -page 91, left-hand column	1-18

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Present claims 1 - 14 and 16 - 18 relate to compounds defined by reference to a desirable characteristic or property, namely "antihistamine" and "osmotic pressure-controlling agent". The claims cover all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the compound by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the compounds listed in claim 15 in combination with ciclesonide.

Furthermore, present claims 1 - 14 and 16 - 18 relate to an extremely large number of possible compounds ("functional derivatives thereof" and "water soluble polymer substance") resulting in a lack of disclosure within Article 5 PCT.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.